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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087879,139	06/19/97	MERRIL L	P8026-7004

HM21/1002

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EXAMINER	
WORTMAN, D	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: ~~10/02/98~~
Remailed 4-25-02 Remail 1-10-00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/879,139	Applicant(s) Merril et al.
	Examiner Donna C. Wortman, Ph.D.	Group Art Unit 1643

☒ Responsive to communication(s) filed on *Aug 10, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *31-40* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *31-40* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply - SEQ

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The request filed on 8/10/98 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. is acceptable and a CPA has been established. An action on the CPA follows.

Claims 31, 32, 34-37, 39 and 40 have been amended in Paper No. 8. Claims 31-40 remain pending and under examination.

Applicant's remarks regarding the obviousness double patenting rejections in the previous Office action have been noted and these rejections are withdrawn.

Applicant is requested to update the status of parent application(s) to which reference is made in the first sentence of the specification.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given the same time period within which to comply with the sequence rules, 37 CFR 1.821 - 1.825, as is available to respond to this Office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the response to the undersigned. Applicant is

requested to return a copy of the attached Notice to Comply with the response.

Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. In the amendment filed 12/12/97, applicant has used underlining in such a manner that it is unclear to the examiner whether the underlining is intended to appear in the patent. The underlining is unclear because in the subsequent amendment filed 8/10/98, underlining is apparently used to indicate inserted material. If underlining is intended to appear in the claims in the published patent, such intention must be clearly indicated in applicant's reply to this notice. It is suggested that any underlined material intended to indicate genus and/or species of bacteria be deleted and replaced by italicized material in order to avoid confusion.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an infectious disease caused by bacteria in non-human animals, does not reasonably provide enablement for treating an infectious disease caused by bacteria in a human patient. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides guidance for selecting bacteriophage that have a longer half-life by passaging through an animal and then using these bacteriophages to treat an infectious disease caused by bacteria in animals of the same species as the animal in which the bacteriophage selection was done. There is no guidance particularly directed to selecting bacteriophage by passaging through humans, nor is there guidance for selecting bacteriophage by passaging through an animal or animals and then using the animal-selected bacteriophage to treat humans. There is no indication that a particular animal model is suitable for obtaining results related to bacteriophage treatment that could reasonably be extrapolated to treating disease in a human patient. One of skill in the art would require more than mere assertion that such procedures might be performed in order to successfully treat infectious disease in humans, given the state of the art at the time the invention was made with respect to using bacteriophage to treat human disease, the lack of knowledge of how the human immune system reacts to the presence of bacteriophage, and the unpredictability inherent in the art of treating diseases in humans. In the absence of factual evidence that the disclosed methods for selecting bacteriophage and using them for treatment are also suitable for extrapolation to selecting bacteriophage for use in human treatment, the

specification is not seen to be enabling for human treatment using bacteriophage as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Donna C. Wortman, Ph.D.
Patent Examiner

September 30, 1998